IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA and REGENXBIO INC.,

Plaintiffs,

v.

SAREPTA THERAPEUTICS, INC. and SAREPTA THERAPEUTICS THREE, LLC,

Defendants.

C.A. No. 20-1226 (RGA)

JURY TRIAL DEMAND

PLAINTIFF REGENXBIO INC.'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)

Dated: November 20, 2020

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Sarepta's motion fails to cite, let alone address, the controlling authority that, when applied to the present facts, compels the finding that Sarepta's activities fall outside the statutory Safe Harbor of 35 U.S.C. § 271(e)(1). When examined under that proper legal framework, as set out by the Federal Circuit in *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265-66 (Fed. Cir. 2008), Sarepta's activities are not protected by the Safe Harbor. Moreover, and while secondary to this dispositive argument, Sarepta asks the Court to make factual findings in its favor on a motion to dismiss. For these two independent reasons, Sarepta's motion should be denied.

I. SUMMARY OF THE ARGUMENT

Under the controlling case law applied to the allegations made by Plaintiffs Regenxbio Inc. and The Trustees of the University of Pennsylvania ("Plaintiffs") in their Complaint, Sarepta's activities are not protected by the Safe Harbor provided by 35 U.S.C. § 271(e)(1).

1. It is undisputed that Sarepta uses cultured host cells covered by U.S. Patent No. 10,526,617 (the "'617 patent"), owned by Plaintiffs, to produce its gene therapy products, including SRP-9001 and -9003 (referred to collectively herein as "SRP-9001.") While SRP-9001 requires FDA approval for marketing, it is also undisputed that the cultured host cells used to create SRP-9001, and claimed in the '617 patent, do not. (Compl. (D.I. 1) at ¶ 34.)

2. The Federal Circuit in *Proveris* held that the Safe Harbor did not apply to the use of a patented product in connection with FDA regulatory submissions, where, like here, the patented product was not subject to FDA premarket approval and thus was not a "patented invention" within the scope of 35 U.S.C. § 271(e)(1). 536 F.3d at 1265-66. Moreover, in *Proveris*, like here, the patent-in-suit was not eligible for a patent term extension afforded by 35 U.S.C. § 156. *Id.* Denying Sarepta's motion is also consistent with the policy that underlies the Safe Harbor. The Supreme Court in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990), explained that Sections 156 and 271(e)(1) were enacted in order to eliminate two unintended

distortions of the effective patent term resulting from premarket approval required of certain products. In refusing to apply the Safe Harbor, the Federal Circuit in *Proveris* found that neither distortion applied to the patent and product at issue, since premarket approval was not required. 536 F.3d at 1256-66. That same reasoning applies here, as the cultured host cell claimed in the asserted '617 patent is not subject to FDA approval. Nor is the asserted '617 Patent extendable under Section 156.

3. Sarepta's motion should also be denied because it rests on factual disputes with regard to Sarepta's commercial supply to Roche and their related agreement, disputes which Sarepta improperly asks the Court to resolve in its favor at the motion to dismiss stage. When the allegations in Plaintiffs' Complaint are taken as true, and all factual inferences resolved as they must be in Plaintiffs' favor, Sarepta's commercial supply of SRP-9001 likewise falls outside the Safe Harbor.

II. STATEMENT OF FACTS

The product that Plaintiffs accuse of infringing the '617 patent is not a product that is in clinical development. Sarepta's motion confuses this issue by focusing on the clinical development of SRP-9001. (Mot. (D.I. 13) at 5.) But the Complaint in this case does not allege that the SRP-9001 product infringes the '617 patent. The Complaint instead alleges that cultured host cells used to produce SRP-9001 infringe the '617 patent. (Compl. (D.I. 1) at ¶ 28.)

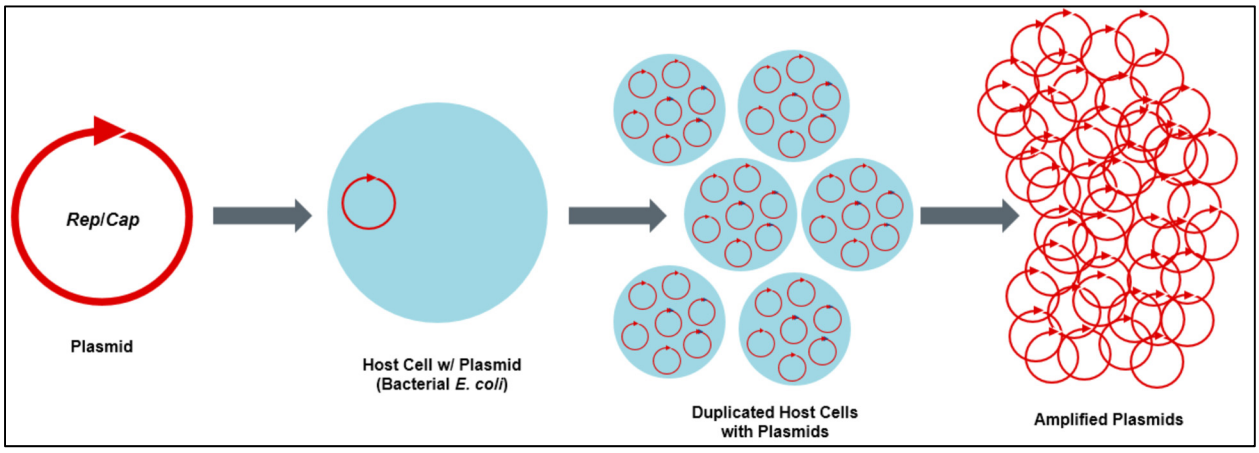
While the Court need not rely upon any materials outside the Complaint to decide the motion, we believe it would be beneficial to the Court to provide a more detailed overview of the technology in this case. By way of background, the process of making therapeutics such as SRP-9001 typically uses two types of "host cells," both of which are alleged to infringe the '617 patent. (*See generally id*. at ¶¶ 16-18, 28-31.) Therapeutics such as Sarepta's SRP-9001 are referred to as

rAAV vector products. rAAV vector products are manufactured by making plasmids in bacterial host cells, transfecting (inserting) the plasmids into a mammalian host cell, and then culturing the host cell to produce the rAAV vector product. (*See, e.g.*, *id*. at ¶ 30 (including informational video link).)

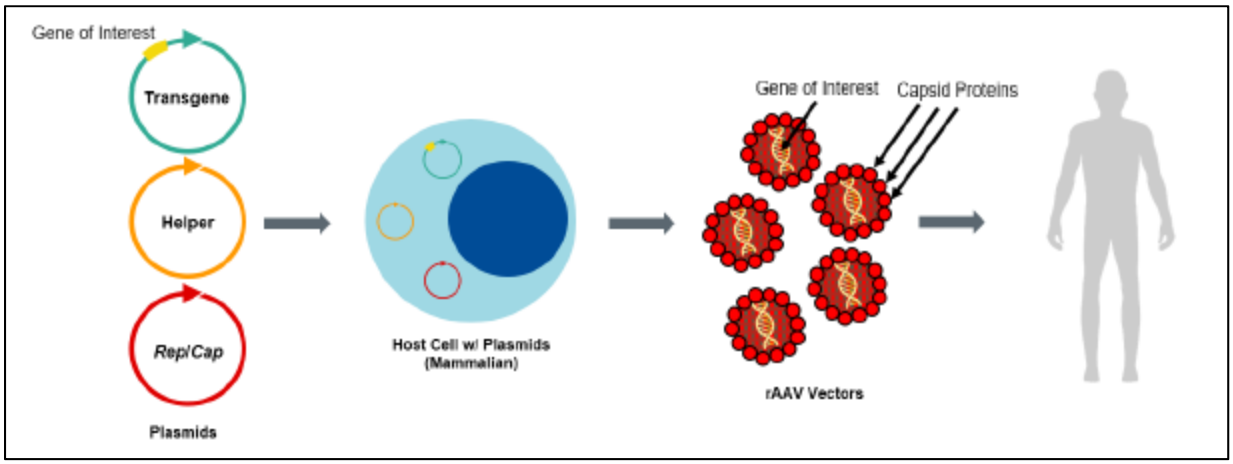
The manufacturing of the rAAV vector products often uses what is referred to as a three-plasmid system (or "triple transfection method"). In that method, three separate recombinant DNA plasmids are engineered: (1) a "transgene" plasmid, containing the transgene of interest; (2) a "helper" plasmid, containing helper genes needed for production and assembly of the rAAV vector; and (3) of particular interest to this lawsuit, a "*rep/cap*" plasmid, containing the *rep* gene needed to replicate the transgene, and the *cap* gene needed to produce the capsid proteins (VP1, VP2, and VP3) that ultimately package the replicated transgene. (*See, e.g.*, *id*. at ¶ 30 (including informational video link).)

The process of manufacturing rAAV vector products begins by preparing the plasmids. Each plasmid is made separately and kept isolated from other plasmids during this stage in the process. To increase the number of each plasmid type, the plasmids can be transfected into a host cell, often a bacterial host cell. Once transfected, the host cell makes multiple copies of the plasmid DNA; the cells also proliferate in culture making more host cells, further increasing the number of plasmid copies generated. After sufficient time has passed, the engineered host cells may then be lysed (or ruptured) allowing for the amplified plasmids to be collected, isolated, and purified. This process allows for a greater number of plasmids to be made from an initial small number of plasmids. The following graphic depicts the process—the plasmids containing *rep* and *cap* genes are transfected into host cells, the engineered host cells proliferate in culture, and the amplified plasmids are recovered. This same process could be used to separately amplify each of the

plasmids containing the transgene or the other helper genes. Notably, the "*rep/cap*" plasmids made by these host cells are not limited to producing a given rAAV vector product; rather, they can be used with plasmids for a wide variety of transgenes to make a wide variety of rAAV vector products:



Later, the following graphic depicts how the three separate recombinant DNA plasmids are co-transfected into a mammalian host cell (labeled as "Host Cell w/ Plasmids"). Through the triple transfection method, Sarepta additionally makes use of the cultured host cells covered by the '617 patent. (*See* Compl. (D.I. 1) at ¶¶ 28-31.) This is the cultured host cell which then produces the final rAAV vector product, which is the therapeutic used to treat humans:



(*See, e.g.*, *id.* at ¶ 30 (including informational video link).) Sarepta does not dispute that it uses cultured host cells covered by Plaintiffs' patent to produce its gene therapy products. (Mot. (D.I. 13) at 1, 7.)

The claims of the asserted '617 patent protect Plaintiffs' novel cultured host cell technology. The claims are not directed to a potential gene therapy treatment. For example, claim 1 recites:

> 1. A cultured host cell containing a recombinant nucleic acid molecule encoding an AAV vp1 capsid protein having a sequence comprising amino acids 1 to 738 of SEQ ID NO: 81 (AAVrh.10) or a sequence at least 95% identical to the full length of amino acids 1 to 738 of SEQ ID NO: 81, wherein the recombinant nucleic acid molecule further comprises a heterologous non-AAV sequence.

Plaintiffs' Complaint alleges that Sarepta produces its gene therapy products including SRP-9001 in a process that includes making and using the claimed cultured host cell. (Compl. (D.I. 1) at ¶¶ 28-30.) Sarepta does not dispute this fact. To the contrary, Sarepta admits that it uses the cultured host cells in this manner, and acknowledges the allegation in the Complaint that "Sarepta has infringed the '617 patent through its alleged ***use of*** certain 'cultured host cells' ***to make a gene therapy product*** known as 'SRP-9001.'" (Mot. (D.I. 13) at 1 (emphasis added).)

Further, as described above, there are likely two distinct steps used by Sarepta to make SRP-9001 that use a host cell as claimed by the '617 patent: (1) the bacterial host cells used to amplify the "*rep/cap*" plasmid, and (2) the mammalian host cells used to manufacture the final product. (*See* Compl. (D.I. 1) at ¶¶ 28-31.)

Significantly, the Complaint also alleges that the cultured host cells claimed in the '617 patent, and used in Sarepta's manufacturing process, do not require FDA approval. (Compl. (D.I. 1) at ¶ 34.) Sarepta also does not dispute this fact. Nor does Sarepta dispute that, as a matter of law, the term of the '617 patent is not extendable under Section 156.

III. ARGUMENT

A. Safe Harbor Legal Authority

Section 271(e)(1) provides, *inter alia*, that it shall not be an act of infringement to use a "patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs. . . ." 35 U.S.C. § 271(e)(1). Although Sarepta does not address it, the question the Court must resolve to decide Sarepta's motion is whether the phrase "patented invention" in this statutory language covers the cultured host cells that are alleged to infringe the '617 patent. If not, then the Section 271(e)(1) Safe Harbor does not immunize Sarepta from infringement. As discussed below, as a matter of law, the claimed cultured host cells are not a "patented invention" within the meaning of Section 271(e)(1), and Sarepta's motion must be denied.

While the Safe Harbor provides broad protection for certain uses related to the "development and submission of information" to FDA, that protection is not limitless. "Despite the broad contours of the [Safe Harbor] exemption, some activities are outside its protection." *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.,* 809 F.3d 610, 619 (Fed. Cir. 2015) (recognizing "research tools or devices that are not themselves subject to FDA approval may not be covered") (citing *Proveris*, 536 F.3d at 1265-66). Even though the Courts have recognized a number of limitations on Safe Harbor protection, Sarepta fails to cite or discuss any of those key limiting decisions.

One of those decisions is the widely cited and discussed decision in *Proveris*. There, the plaintiff accused Innova of selling an Optical Spray Analyzer ("OSA") to companies that used the OSA solely to obtain data to support FDA approval of the final products. 536 F.3d at 1259. There was no dispute that the use of the OSA was solely related to activities directed to obtaining FDA approval. *Id.* Nonetheless, the Federal Circuit held that the OSA was outside the scope of the

term "patented invention" in Section 271(e)(1). *Id.* at 1265-66. Since the accused OSA was not itself subject to FDA approval, but rather only the product on which the tests were conducted needed such regulatory approval, the Safe Harbor did not apply. *Id.* at 1265 ("Innova's OSA device is not subject to FDA premarket approval . . . . [I]nsofar as its OSA device is concerned, Innova is not within the category of entities for whom the safe harbor provision was designed to provide relief.") Moreover, the Federal Circuit noted that the asserted patent was not extendable under Section 156, and for that additional reason, the Safe Harbor did not apply. *Id.* at 1265-66 ("Because Proveris's patented product is not subject to a required FDCA approval process, it is not eligible for the benefit of the patent term extension afforded by 35 U.S.C. § 156(f).")

In reaching its decision, the court in *Proveris* was guided by the Supreme Court's opinion in *Eli Lilly*. In reviewing the considerations leading to the Hatch-Waxman Act, the *Proveris* court noted how "sections 156 and 271(e)(1) were enacted in order to eliminate two unintended distortions of the effective patent term resulting from premarket approval required of certain products pursuant to the FDCA." 536 F.3d at 1265 (citing *Eli Lilly*, 496 U.S. at 669-70). In *Eli Lilly*, the Supreme Court explained that "the first distortion was the reduction of effective patent life caused by the FDA premarket approval process." *Id.* This was remedied by enactment of Section 156. The "second distortion was the de facto extension of effective patent life at the end of the patent term - also caused by the FDA premarket approval process." *Id.* This was remedied by enactment of Section 271(e)(1).

In reaching its conclusion that the OSA device was not a "patented invention" as that term is used in Section 271(e)(1), the court noted that "in *Eli Lilly* the Court spoke of its interpreting the phrase 'patented invention' in section 271(e)(1) to include all products listed in section 156(f) [i.e., a drug product, medical device, food additive and color additive] as producing a 'perfect

'product' fit' between the two provisions." *Proveris*, 536 F.3d at 1265 (quoting *Eli Lilly*, 496 U.S. at 672). *Proveris* refers to this as a "symmetry" between the two provisions. *Id.* Since the OSA device was neither subject to regulatory approval nor eligible for a patent term extension afforded by 35 U.S.C. § 156, it did "not need the safe harbor protection afforded by 35 U.S.C. § 271(e)(1)." *Id*. at 1266.

B. Sarepta's Use of Cultured Host Cells to Produce SRP-9001 is Not Covered by the Safe Harbor

This reasoning of *Proveris* controls here, and requires a finding that Sarepta's use of cultured host cells to produce SRP-9001 is outside the Safe Harbor. Sarepta's motion should therefore be denied.

1. The Cultured Host Cell Claimed in the Asserted '617 Patent is Not Subject to FDA Approval

The accused product in this case is not subject to FDA regulatory approval. While Sarepta's SRP-9001 biologic product requires FDA approval, the cultured host cells that Sarepta uses to make that product do not. (Compl. (D.I. 1) at ¶ 34.) Sarepta does not dispute this fact in its motion. These cultured host cells, not SRP-9001, are accused of infringement in Plaintiffs' Complaint. (*Id.* at ¶¶ 28-31). As the court in *Proveris* recognized, the fact that the patented product is not subject to FDA premarket approval removes it from Safe Harbor protection. 536 F.3d at 1265. Like defendant Innova in *Proveris*, insofar as this type of "patented invention" is concerned, Sarepta "is not within the category of entities for whom the safe harbor provision was designed to provide relief." *Id.*

District courts following *Proveris* have reached similar conclusions when dealing with the Safe Harbor and its applicability to products not themselves subject to regulatory approval. Although no court in this district has yet addressed this point, the reasoning of other courts is sound. For example, in *PSN Ill., LLC. v. Abbott Labs.*, No. 09cv5879, 2011 U.S. Dist. LEXIS

108055 (N.D. Ill. Sept. 20, 2011), the patents-in-suit related to receptors that Abbott was using to develop drug candidates that themselves required FDA approval. Like the cultured host cells claimed in the '617 patent, the patented receptors were used by defendant Abbott to then obtain a therapeutic agent. *Id.* at *3-6. In holding that the Safe Harbor did not apply, the court relied on *Proveris,* and *Proveris's* analysis of *Eli Lilly* and the legislative intent behind Section 271(e)(1). *Id.* *9-11. Since the patented receptors were not subject to FDA approval, and "[defendants] were using [them] to develop their own" product, the receptors were not a "patented invention" within the meaning of Section 271(e)(1). *Id.* at *18. Like the defendant in *PSN*, Sarepta is using cultured host cells covered by Plaintiffs' patent to produce its therapeutic product, SRP-9001. *See also ISIS Pharms., Inc. v. Santaris Pharma A/S Corp*., No. 11cv02214BTM(KSC), 2012 U.S. Dist. LEXIS 134107, at *11-14 (S.D. Cal. Sept. 18, 2012) (denying summary judgment of non-infringement and rejecting defendant's Safe Harbor defense because the patents-in-suit covered methods of modifying biologic molecules where only the final products, not the accused products, were subject to FDA approval).

The three cases that underpin Sarepta's motion are readily distinguishable on this ground. Unlike the "patented invention" of the '617 patent, *Medical Diagnostic Laboratories*, *Telectronics Pacing Systems*, and *AbTox* each involved patented products that themselves ***were*** subject to FDA regulatory approval. In *Medical Diagnostic Labs., LLC v. Protagonist Therapeutics, Inc*., 298 F. Supp. 3d 1241, 1245, 1251 (N.D. Cal. 2018), the accused products were polypeptides used to treat various diseases, which were subject to FDA approval. Similarly, in *Telectronics Pacing Sys. v. Ventritex, Inc*., 982 F.2d 1520, 1521 (Fed. Cir. 1992), the accused products were implantable defibrillators that themselves required FDA approval. And in *AbTox Inc. v. Exitron Corp*., 122 F.3d 1019, 1020 (Fed. Cir. 1997), the accused product was a medical device, which required

approval by FDA, used to sterilize medical equipment. The Supreme Court in *Eli Lilly* held that medical devices such as the one at issue in *AbTox* are subject to the Safe Harbor. *Id.* at 1028-29.

These cases are thus inapplicable here, where there is no dispute that the cultured host cells used by Sarepta are not subject to FDA approval.

2. The '617 Patent is Not Extendable Under Section 156

The '617 patent is not subject to a term extension under Section 156. This too is undisputed. Section 156 permits a term extension for, among other things, a patent covering a product that "has been subject to a regulatory review period before its commercial marketing or use." 35 U.S.C. § 156(a). The statute defines "product" as including "drug product," which means "the active ingredient" of a new drug or biological product. 35 U.S.C. § 156(f). In *Proveris*, after holding that the Safe Harbor was not applicable because the OSA was not subject to regulatory approval, the Federal Circuit also recognized that the patentee was "not eligible for the benefit of the patent term extension afforded by 35 U.S.C. § 156(f)." 536 F.3d at 1265-66. Because the cultured host cells claimed in the '617 patent are likewise not eligible for a patent term extension under Section 156, this Court should reach the same result and find that the Safe Harbor does not apply.

Here again, the *AbTox* case on which Sarepta relies is likewise readily distinguishable. *AbTox* involved a Class II medical device that was subject to FDA approval for use in sterilizing medical instruments. 122 F.3d at 1027. In *AbTox*, the court found that the Safe Harbor did apply because the Supreme Court in *Eli Lilly* had earlier ruled that "all classes of medical devices fall within the plain meaning of section 271(e)(1)." *Id.* at 1029 (citing *Eli Lilly*, 496 U.S. at 671-72). Thus, Class II devices, even though ineligible for patent term extension under Section 156, were subject to the Safe Harbor. *Id.* Indeed, the *Proveris* court specifically recognized that the *AbTox* decision was premised on the holding in *Eli Lilly* that held the term "patented invention" in Section

271(e)(1) included "any medical device." *Proveris*, 536 F.3d at 1263. The cultured host cells accused in this case are plainly not a "medical device." Later courts have likewise recognized that *AbTox* does not extend Safe Harbor protection beyond those products listed in Section 156, which specifically includes medical devices. *See, e.g.*, *Infigen, Inc. v. Advanced Cell Tech., Inc.*, 65 F. Supp. 2d 967, 980 (W.D. Wis. 1999).

C. Sarepta's Commercial Supply of SRP-9001 is Not Covered by the Safe Harbor, and its Motion Rests on Factual Disputes That Cannot be Resolved in Sarepta's Favor on a Motion to Dismiss

In Sections IV.B. and C. of its motion, Sarepta improperly asks this Court to make factual findings in its favor. This is not proper at the Rule 12 stage, where the court must accept as true the allegations in the Complaint, viewed in a light most favorable to Plaintiffs. "When reviewing a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must accept the Complaint's factual allegations as true." *Peloton Interactive, Inc. v. Echelon Fitness, LLC*, No. 19-cv-1903-RGA, 2020 U.S. Dist. LEXIS 118945, at *3 (D. Del. July 6, 2020); *see also United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-cv-755-RGA, 2020 U.S. Dist. LEXIS 205150, at *2-3 (D. Del. Nov. 3, 2020) ("A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in the Complaint as true, and viewing them in the light most favorable to the complainant, a court concludes that those allegations 'could not raise a claim of entitlement to relief . . . .'") (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007)).

Sarepta's motion implicitly requests that the Court make factual findings on, for example, the scope of the Roche agreement and the definition of "commercial supply." That is plainly improper at this stage. Citing Sarepta's public filings, Plaintiffs' Complaint alleges that Sarepta has made and/or will make a "commercial supply" of SRP-9001 using the cultured host cells of the '617 patent. (Compl. (D.I. 1) at ¶ 36.) In its motion, Sarepta appears to concede that manufacture of a therapeutic agent for commercial use is not a use "reasonably related" to

development and submission of information for regulatory consideration. Indeed, recent authority shows that commercial supply of a product may not be considered reasonably related to obtaining FDA approval, and thus is outside of Safe Harbor protection. *See Amgen Inc. v. Hospira, Inc.*, 336 F. Supp. 3d 333, 344-45 (D. Del. 2018) (Andrews, J.) (dismissing Hospira's motion for judgment as a matter of law and noting, "I agree with Amgen and conclude that substantial evidence supports the jury's verdict that not all of Hospira's drug substance batches are protected by the safe harbor."), *aff'd*, 944 F.3d 1327 (Fed. Cir. 2019). Sarepta fails to cite this or any authority regarding commercial manufacturing supply and the application of the Safe Harbor.

Plaintiffs' Complaint also alleges that Sarepta entered into an agreement with F. Hoffman-La Roche Ltd. ("Roche") to develop and commercialize SRP-9001 outside the United States. (Compl. (D.I. 1) at ¶ 35.) The Complaint further alleges that both Sarepta and Roche are or will be seeking regulatory approval for SRP-9001 outside the United States. (*Id.*) Courts have found that activities related to obtaining regulatory approval outside of the United States may fall outside the protection of the Safe Harbor. *See, e.g.*, *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 207-08 (D.N.J. 1994) (denying summary judgment that shipments of infringing products to foreign regulatory agencies is protected by the Safe Harbor and noting that "[i]t may be true that most of the vials were used to generate data for the FDA, but in this instance, some vials were clearly used for other purposes.") Sarepta fails to address this point in its motion. Notwithstanding the scope or timing of Sarepta's commercial supply and foreign regulatory activities, the court at this stage must accept the allegations in Plaintiffs' Complaint as true and view them in a light most favorable to Plaintiffs. When viewed in the proper light, Sarepta's motion must be denied.

D. Sarepta's Failure to Apply the Proper Legal Framework Makes its Request for Dismissal With Prejudice Futile

To the extent the Court is inclined to grant Sarepta's motion despite its significant flaws, the Court should deny Sarepta's request that the Court dismiss Plaintiffs' Complaint with prejudice. (Mot. (D.I. 13) at 14-16.) As explained herein, Sarepta failed to address the issues raised in its motion under the correct legal framework. Under that correct legal framework, there are, at the very least, additional facts regarding Sarepta's activities with the cultured host cells covered by the '617 patent that could be pled to support Plaintiffs' claims here. Sarepta's request for dismissal with prejudice should therefore be denied.

IV. CONCLUSION

Sarepta's motion fails to address the legal authority controlling to the parties' dispute, which when applied, demonstrates that Sarepta's infringing activities fall outside the Safe Harbor. For that reason, and because Sarepta improperly requests the Court make factual findings in its favor at the Rule 12 stage, Plaintiff Regenxbio respectfully requests that the Court deny Sarepta's motion to dismiss Plaintiffs' Complaint.

Dated: November 20, 2020

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